GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES AND CONSUMER PRODUCTS

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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Notice of Proposed Rulemaking; Docket No. 02N-0278.

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide comments on the proposal of the Food and Drug Administration ("FDA") to implement section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"), which provides for prior notice of imported food.

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

02N-0278 C165

1. General Comments

GMA and its member companies share with the FDA the goal of enhancing the security of the food supply. Each of GMA's member companies has a deep and abiding commitment to food safety and food security. Our evaluation of FDA's proposals to implement the Bioterrorism Act has been heavily influenced by the commitment we share with FDA to provide a safe and secure food supply to the American people.

GMA well understands the magnitude of the undertaking to develop a workable system of prior notice in the short time available to FDA under the Bioterrorism Act. It is apparent that FDA has devoted considerable effort and thought to the prior notice proposal. Nevertheless, GMA is compelled to conclude that the prior notice system contemplated by the proposal is not workable and must be substantially revised before adoption. It appears to GMA that FDA has sought to implement section 307 of the Bioterrorism Act too expansively and assumed, without basis for the assumption, that both it and the affected industries are capable of adjusting their practices and procedures to conform to the proposed prior notice system without significant disruption in commerce and, thus, the movement of food from production to sale and consumption.

We discuss our concerns with the proposed prior notice system in detail below, but, in short, FDA is seeking considerably more information than is reasonable or necessary to create a functioning prior notice system and has provided for too rigid a model to accommodate all of the multiple ways in which food is imported into the United States. GMA is concerned that without modification, the prior notice system will incur a "systemic failure" with shipments of food from outside the United States unable to be entered in reasonable time periods and FDA no better able to identify "high risk" shipments than without a prior notice system at all. Part of the difficulty with the prior notice proposal stems from FDA's effort to convert a provision in the Bioterrorism Act intended by the Congress to be an aid to FDA in its efforts to ensure the <u>security</u> of the food supply into a provision to enhance the level of compliance of imported products with all of the requirements that apply to food. We believe that existing procedures, including the FDA OASIS system, are more than adequate for the purpose of ensuring compliance with general food requirements. We suggest that FDA revisit the objectives and purposes of the prior notice system to develop a final regulation that seeks only to achieve the critically important goal of the enhancement of food security.

In GMA's comments on the proposal for facility registration, brief mention was made of the risk of systemic failure due to the complexity of the information requirements. Although we believe that there is such a risk in the registration context, it is a modest risk. In contrast, the risk in the prior notice context is material and thus extremely worrisome.

Systemic risk has been described as "the risk that a system fails to perform because of the ways in which its various components interact."[1] The quantity of information that is called for under the prior notice proposal, the time at which that information is required, the need for fundamental changes in the way in which various inter-related businesses operate, the rigidity of the requirements for the provision of the information to FDA, the inflexibility of the time periods for the provision of the information, the lack of provision to change information that has been provided when change is endemic to the business, and the complexity of the system that FDA must have to incorporate all of the information into its decision-making, all suggest a strong likelihood that the multiple component parts of the prior notice system will not interact in a seamless and efficient way, leading to systemic failure. The consequences of systemic failure cannot be overstated.

In its pre-proposal comments, GMA expressed concern about this precise point. We stated:

> The prior notice requirement has great potential to interfere with the movement of food into the United States. If not implemented carefully and with particular attention paid to the practicalities of the importation of food from hundreds of countries, by land, air, and water, there is the very real possibility that ports of entry will resemble massive food bazaars in an underdeveloped country as food piles up in confusion over whether and when notice was provided.

The concern expressed in the pre-proposal comments is even more strongly felt in light of the overly complex prior notice proposal that FDA has issued.

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[1] David A. Hennessy, Jutta Rosen, and Helen J. Jensen, "Systemic Failure in the Provision of Safe Food," Working Paper 02-WP 299, Center for Agricultural and Rural Development, Iowa State University, April 2002, at 2. Available online at www.card.iastate.edu (accessed, March 18, 2003).

In the balance of our comments, we describe in detail the concerns we have about the proposal and suggest ways to address those concerns. All of the comments should be considered with this overriding concern in mind: the proposed system is unduly complex and rigid and creates a real potential for a failure of the entire prior notice system. A workable prior notice system must be simple and flexible and fully take account of commercial feasibility. Working within the confines of the current proposal, FDA must redesign the prior notice system.

2. *Specific Comments*

a. *The Bioterrorism Act Limits The Information in a Prior Notice*

The purpose of the prior notice is to provide FDA with sufficient information about food products to be offered for importation into the United States to permit the agency to make informed and timely decisions whether to examine the products. Section 307 of the Bioterrorism Act specified the information to be contained in a prior notice as: the identity of the article of food, manufacturer and shipper, grower, if known, originating country, country from which the article was shipped, and the anticipated port of entry. These seven items reflect the considered judgment of the Congress as to what information was reasonably necessary for FDA to carry out the function for which the prior notice was designed. There is no language in section 307 to support an expansion of the information required in a prior notice beyond that specified in section 307. Nevertheless, relying on section 701(b) of the Federal Food, Drug, and Cosmetic Act, FDA has asserted essentially that the information specified by Congress in section 307 is merely a starting point for consideration of what a prior notice might contain.

GMA disputes FDA's reading of the Bioterrorism Act and objects to the inclusion of extra-statutory information in the prior notice requirement. Except where necessary to further articulate a statutory requirement (for example, to state what information constitutes the "identity of the article"), FDA does not have the authority to expand the information in a prior notice beyond that which is set forth in section 307. Section 701(b) does not grant to FDA the authority to supercede specific statutory language. If the Congress intended for FDA to do what it has proposed, it would have included, after specifying the information that it thought important, language such as "such other information as the Secretary determines by regulation to be necessary to carry out the function of this section." There is no such language, of course, in section 307.

FDA's interpretation of its authority to expand the information in a prior notice beyond the statutorily specified information fails to give the decisions of the Congress appropriate deference. Again, if Congress wanted FDA to determine what should be in a prior notice, it could easily have so legislated. But, here, as in numerous other places in the Bioterrorism Act, Congress legislated with specificity with the effect that FDA's authority is constrained.

b. *FDA Proposes to Require Far More Information Than is Needed*

In addition to the fact that FDA does not have the authority to expand the required information in a prior notice beyond the information specified in section 307, FDA fails to establish that the additional information that it proposes to require is necessary to effectuate the purpose of prior notice. Thus, even if FDA had authority under section 701(b), it has not made the case that the additional information is "necessary for the efficient enforcement of the Act." Indeed, the information that FDA proposes to require beyond that called for under the Bioterrorism Act and the time period in which FDA expects to obtain that information are not consistent with efficiency in any context.

An example will illustrate how FDA has failed to create a workable system of prior notice. If the system created is not workable, it cannot fairly be said to result in "the efficient enforcement of the Act." Envision a production facility located in Canada approximately one hour north of the U.S. border. The facility runs two shifts and product is typically loaded immediately after production directly onto trucks for transportation to the United States. Under the proposal, the prior notice will need to be submitted by noon of the day before the truck is due to arrive at the port of entry. Yet, the prior notice would be required to contain, among other extraneous information, the lot or production codes of the article of food to be imported. In the scenario described, that information is not reasonably known until the truck is loaded. Even if the prior notice were filed immediately after the truck was loaded, the notice would not be effective for a day or more (a notice filed at 4 p.m. on Monday would not be timely for a Monday or Tuesday arrival at the port of entry). Is there any "efficiency" in requiring that the fully loaded truck sit for two days at the facility (or even worse, at the port of entry)? Are the objectives of the prior notice system enhanced by the interruption in the flow of goods that such a system unavoidably creates?

It is conceivable that the system that FDA has proposed will increase the risks to the security of the food supply, rather than add to it. If fully loaded trucks are required to delay their departure or arrival at ports of entry to comply with

unreasonable prior notice requirements, the opportunity for malicious activity involving the product on those trucks increases. In contrast, it is consistent with the objective of food security for the trucks to be loaded and then to proceed without interruption or delay to their destination.

In determining whether information beyond that which is specified in the Bioterrorism Act is needed to effectuate the purposes of the Bioterrorism Act and is consistent with the "efficient enforcement of the Act," FDA must assess not only what it envisions it might do with the additional information, but also what are the practical consequences of requiring the information. The "efficient enforcement of Act" requires not only that there be some regulatory function that is aided by the requirement (and GMA does not concede that the extra-statutory information that FDA proposes to require will aid anything) but that the operations of the food and related industries not be impeded.

To be clear, GMA is not suggesting that *any* changes in food industry practices that might be required as a result of having to comply with the prior notice requirement are inherently unreasonable. In fact, we recognize and accept that the food industry will need to make some changes in order to achieve the shared goal of increased security for imported food. At the same time, FDA cannot justify any requirement that it might envision by resorting to the mantra that "Congress intended for there to be changes in 'business as usual.'" Each element of the prior notice system must be assessed against a dual standard: what is gained by the inclusion of the element and what are the practical consequences of the inclusion? The only requirements that can be justified are those that provide substantial benefit at an acceptable burden. This test has not been met, as many of the proposed elements of the proposed prior notice system do not produce a major benefit in terms of food security while they impose difficult and, in some cases, impossible burdens, on the food manufacturers who have to comply.

Thus, even if FDA has the authority to require the inclusion of data and information beyond that specified in the Bioterrorism Act –and we do not believe that it does – it has completely failed to justify the inclusion of that information. The final regulation on prior notice should be limited to the information that Congress determined was needed.

c. *FDA Has Failed to Coordinate the Prior Notice Requirement with Existing Customs Service Requirements*

Perhaps the most common theme in the pre-proposal comments submitted by the food industry was the compelling need for FDA to coordinate with the Customs Service to create an integrated notice system. At the pre-proposal stage, many in the food industry – justifiability, as it turns out – were concerned that FDA would create a prior notice system that is duplicative of the existing Customs entry system. Not only did FDA not develop a prior notice system that melds with the existing Customs regime, but also it created its own highly complex system that simultaneously makes compliance with the existing Customs system more difficult. This cannot be what the Congress intended when it required, in section 307 that FDA consult with the Secretary of Treasury (under whose jurisdiction was the Customs Service at time of enactment of the Bioterrorism Act) on the regulations to implement section 307.

Under the existing Customs entry system, information is entered which, in the case of imports of food products subject to FDA's jurisdiction, is provided to FDA through the OASIS system. It was hoped that FDA would be able, in consultation with the Customs Service, to develop a prior notice system that took advantage of the existing information flow between the food industry and importers, on the one hand, and the Customs Service and FDA on the other. Regrettably, this is not what has happened. Instead of the integrated system that was hoped for, if the proposal is finalized as written, companies will now have to redo their mechanisms for compliance with Customs requirements and create mechanisms to comply with the prior notice requirement. The burdens that this creates and the disruption to commerce that will inevitably follow are ignored or minimized by FDA.

GMA recognizes that even with the best of intentions and substantial effort, it may not have been possible for FDA to create a prior notice system that is integrated with the existing Customs entry system. Nevertheless, we suggest that once the judgment was made that it would not be possible to accomplish that goal in the available time and, thus, that dual systems would, at least for the foreseeable future, be required, FDA should have turned to the development of as simple a prior notice system as possible that would meet the statutory requirements. Then, both FDA and the industry could have gained valuable experience with the prior notice system, identified and corrected problem areas, and determined what additions or enhancements to the system would make sense. This process could well occur along side of the ongoing

development by the Customs Service of a revised entry system (ACE) that might well be the basis for a single time and point of data entry for notice to federal regulators of impending importation of food products.

The failure to integrate with the Customs entry system and the resulting dual systems and multiple points and times of data entry is one of the places where the risk of systems failure arises. FDA appears to have assumed that the information that is currently submitted to Customs for entry purposes is readily available at an earlier time (perhaps more than two weeks earlier) than is required by the Customs Service and that this information can, therefore, be easily included as part of prior notice. This will often not be the case.

d. *The Time Periods for Prior Notice and Amendments and Updates Are Not Workable*

Section 307 of the Bioterrorism Act provides that in determining the time period for prior notice, FDA is to consider, among other things, "the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, [and] the types of food imported into the United States...." (section 801(m)(2)(A) of the FDC Act, as added by section 307 of the Bioterrorism Act) It is difficult to determine under the proposal how FDA has factored those considerations into the prior notice proposal.

In the case of food products produced in Canada or Mexico, which comprise a substantial portion of all food imports, the time between the completion of production, and then loading and transportation to the U.S. port of entry, is often considerably less than the time required for prior notice. Because of the extensive data that FDA proposes to require in a prior notice, it will often not be possible for prior notice to be submitted before the transportation vehicle is loaded. Yet, given the short distances between many of these facilities and the U.S. border, the notice cannot possibly be submitted in time to permit the orderly movement of the vehicle to the border for clearance into the United States.

FDA appears to have recognized this problem, but its solution – the ability to anticipate the need for and to amend a notice – does not solve the problem. The precision and the quantity of information required in a prior notice and the limitations on the ability to amend the notice make FDA's solution to this problem ineffective. Under the proposal, an amendment to a prior notice is permitted only if the person who submitted the prior notice anticipated the

need to amend and so indicated on the initial notice. Even then, the amendment may only provide limited greater specificity about the identity of the articles of food that was previously provided in the initial notice. Only in very limited circumstances will this amendment process work.

The amendment process, as proposed by FDA, will not work because it requires that food companies possess information about shipments before that information can reasonably be obtained and it does not permit them to amend a notice in a meaningful way, even when they do have the information. If a facility is located only an hour or so from the U.S. border, it simply cannot comply with the prior notice requirement, as proposed, without incurring major and recurring disruption to its business. Moreover, such a facility would not be able to use the amendment process to solve its problems with the initial prior notice.

Assume that a facility in such a location produces a variety of snack foods and that it transports its products to the United States by truck, several of which depart for the United States each day. The mix of products that is loaded onto each truck is determined by production schedules and orders from distributors and retailers. Typically, the items to be loaded and the quantity of each are not known until shortly before the truck arrives at the loading dock. Even if prior notice is provided at the first available opportunity, the notice will not be timely for at least a day (if the truck is loaded and the notice is filed before noon) or two days (in the case of trucks loaded after noon). There is no practical way for a company in this situation to "work around" the notice requirement: it cannot "guess" at what its customers want and then ship goods based on that "guess." It cannot know the lot and production numbers until the truck is loaded, so it cannot accelerate the timing of the prior notice. It could, of course, load trucks and then have them sit idle for a day or two while prior notice is filed and takes effect, assuming it has space for that and can feed and house the drivers. It makes no sense to put companies through this situation.

Under the proposal, FDA would permit amendments related to common or usual name, trade or brand name, lot or production codes, and quantity. However, because FDA proposes to require that the intention to amend be included in the initial notice, the ability to amend a prior notice is far more limited than would appear to be the case. In the preamble and the proposed regulation, FDA makes clear that it envisions the amendment process as applying largely to the importation of fresh produce and fish grown or caught in Canada or Mexico. This limitation makes the amendment process largely irrelevant for producers of processed foods in those two neighboring countries, even though they need a workable amendment process as much as producers

of fresh produce and fish do. Under the proposal, there is no provision –other than the filing of a new notice – to account for the circumstance in which there are unanticipated changes in the articles of food that are contained in a shipment. The process of moving food from foreign locations to the United States is not nearly as precise as FDA assumes. Without a workable amendment process, disruptions in commerce are inevitable.

These results are not mandated by the prior notice requirement, but flow entirely from the prior notice regime that FDA has developed. There are better models for prior notice that FDA should adopt that would solve these types of problems without undermining the prior notice system. We provide several suggestions on how to accomplish this below in the section entitled "Ways to Create a Workable Prior Notice System."

e. *The Information in a Prior Notice Should Be Narrowed*

The quantity and complexity of information that FDA would require in a prior notice is unreasonable and not supported by any compelling public health/food security need. As noted above, much of the information that FDA would require is not set forth in the Bioterrorism Act and cannot be justified as consistent with FDA's statutory authority. As we discuss above, we believe that the quantity and complexity of the information called for in a prior notice creates a very real possibility of systemic failure.

Some of the information called for in a prior notice appears to be optional. In the final regulation, FDA should clarify which information is mandatory and which is optional.

The starting point for fixing the prior notice system is to tailor the information requirements so companies can reasonably be expected to acquire and file the information with FDA on a timely basis. The food security objective of the prior notice system can be achieved with considerably less information than that required under the FDA proposal.

(i) **Identity of the Article of Food**

The Bioterrorism Act requires that the article of food to be imported into the United States be identified. FDA has interpreted this to be that the article has to be identified with absolute precision. Neither the Bioterrorism Act nor the purpose of the prior notice system requires this result.

Under section 1.288(e)(1) of the proposal, FDA would require five data elements to identify the article: (1) complete FDA product code; (2) common or usual or market name; (3) trade or brand name if different from common or usual or market name; (4) quantity of food by package size; and, (5) lot or production codes. The workability of the proposal would be greatly enhanced if the description of the article for purposes of the initial notice was in general terms ("fresh vegetables" or "seafood") and a more specific identification was provided through an amendment.

FDA could also materially improve the workability of the proposal if it narrowed the information required to identify the article of food to: (1) FDA product code (or codes); (2) common or usual name; and (3) maximum quantity of the article. The person filing the notice should be permitted, but not required, to include the trade or brand name.

Specifying the precise quantity by each package size does nothing but unduly complicate the notice. It is difficult to imagine a scenario in which it would be critical for FDA to know in advance that a truck contains a precise quantity of several different size bags of a snack food or different size cans of canned peas. Recall that the purpose of the prior notice is to enable FDA to make informed decisions whether to inspect or examine product offered for importation. We cannot conceive of a set of facts that would cause that decision to be made based on the quantity of each package size. Moreover, having the package size information does not facilitate the inspectional process. If FDA had the information and a truck arrives at the border, how does FDA determine whether the information is correct without causing the entire truck to be unloaded? And, if FDA does that, it has already made the decision to inspect the shipment.

Instead of requiring the precise quantitative information that is called for under the proposal, FDA should require a specification of the maximum quantity of each article (for example, "not more than 38 pallets of canned peas in 12 and 36 ounce cans"). This more flexible quantitative description of the article of food would meet FDA's needs while easing the prior notice burden on the food industry.

Second, FDA should dispense with the requirement for lot or production codes. As noted above, this information is often not known until the transportation vehicle is loaded with the result that notice cannot be made in time. Equally important is the fact that this information is of no value in deciding whether to inspect an article of food. Moreover, as in the case of the package size information, FDA cannot verify that the lot or production code information is

correct without conducting a complete examination of the shipment. Does FDA intend to cause each truck or rail car to be unloaded and each pallet broken down so that it can compare the lot or production codes on the products with those in the prior notice? If so, at what cost to commerce and to what end?

Third, the trade or brand name of the food is not material to the determination of whether the food should be examined. FDA will know the identity of the manufacturer and that information, along with the description of the food itself, is sufficient to permit an informed decision by FDA.

GMA submits that if FDA has the three data elements that it suggests would identify the article of food – FDA product code, common or usual name, and package sizes and maximum quantity – FDA would be fully able to fulfill its obligations under the Bioterrorism Act.

(ii) **Grower Identity**

The Bioterrorism Act provides that the grower of the article of food to be imported is to be provided in prior notice "if known within the specified period of time " for prior notice." The proposed implementation of this requirement is overly broad.

Under section, 1.288(g), FDA proposes that the "name, address, phone number, fax number, and email of all growers, and the growing location if different from business address" constitute the "grower" information. This proposed requirement is yet another example of excessive data requirements which will create all manner of unintended consequences. For example, does a person who is filing a prior notice "know" the identity of the grower if, in the time period in which the prior notice is being prepared, the name and location of the grower are known, but not the additional information? Will the prior notice been deemed complete if only that information is provided? The Bioterrorism Act makes clear that there is no affirmative obligation to seek out the grower information. If FDA persists in requiring all of the information about growers that is set forth in proposed section 1.288(g), that section should be revised to make clear that a prior notice need only contain that information about the grower that is "known" to the person who is completing the prior notice and that such person is not required to undertake any inquiry to acquire any additional information about the grower.

Section 1.288(g) should be further revised to make clear that the requirement to provide grower information does not apply to processed foods or ingredients.

First, the concept of a "grower" in the case of a processed food or ingredient has no relevance. A processed food or ingredient is not "grown" and there is no significance to the identity of the grower of such a processed food or ingredient. Moreover, when processed foods or ingredients are made from products that were grown, it is commonly the case that the "grown products" are commingled before the food manufacturer receives them. For example, a food manufacturer who makes a grain-based product outside the United States receives grain (or flour), which has been grown on numerous farms located in several different countries and commingled at the grain elevator and milling points. There is no conceivable way to identify any of the grain or flour that is received by that food manufacturer with any grower.

In sum, FDA should: (1) narrow the information that is required to be provided with regard to "grower" identity; (2) clarify that the filer of the prior notice need only provide that information about the grower that is known and need not undertake any effort to obtain additional information; and, (3) exempt processed foods and ingredients from the grower identification requirement entirely.

(iii) Duplication of Information Provided to the Customs Service Should Be Eliminated

Under the proposal, FDA would require that substantially all of the information provided to the Customs Service for entry purposes be re-entered into the prior notice system. This is unnecessary and burdensome.

All of the information that is provided to the Customs Service on imported food is transferred to FDA through the ACS-OASIS interface, albeit in a time period that does not necessarily coincide with the proposed prior notice time periods. To the extent that FDA concludes that it needs this information for prior notice purposes, it is obligated to work with the Customs Service to achieve that result. It is unfair and highly burdensome on the food industry to require it to provide the same information twice. If FDA and the Customs Service are not able in the time available to achieve that result, then FDA should limit the data required for prior notice strictly to that specified in the Bioterrorism Act. Additional but extra-statutory information that FDA believes might be useful to it can be captured from the Customs Service at a later time when the Customs Service has implemented its modernized ACE system.

(iv) "Country of Origin" Should Mean the Same Thing for FDA and the Customs Service

One of the data elements mandated by the Bioterrorism Act for inclusion in a prior notice is the "country from which the article originates." Under proposed section 1.277(c)(4), FDA proposes a definition of "originating country" that it concedes is not the same in all respects as the definition of "country of origin" for Customs Services purposes. In the preamble discussion of this definition, FDA asserts that the Customs Service definition of "country of origin" is not adequate for purposes of the Bioterrorism Act.

It is not at all clear from the preamble discussion why FDA concludes that the definition of "country of origin" used by the Customs Service will not be adequate for purposes of prior notice. There is a substantial body of precedent related to the Customs Service definition of "country or origin." Employing a different definition under prior notice will engender confusion and create an apparent inconsistency between prior notice filings and Customs entry documents. Customs brokers will have an almost impossible task of keeping the nuances of the two definitions in mind as they complete the required notices and filings for the Customs Service and for FDA. Over time, FDA will have to bear an additional burden of developing a body of precedent that explicates "originating country" when that body of precedent already exists. There is no obvious benefit to having two definitions. It is obvious, however, that the proposed approach will cause confusion and error and be wasteful of scarce resources. We urge FDA to use the Customs Service definition of "country of origin" in the prior notice final regulation.

f. *The Time Period for Prior Notice Should Be Made Flexible*

Many of the problems that the food industry is encountering with the prior notice proposal stem from the unreasonably long and inflexible time period for the filing of prior notice.

First, by requiring notice by noon of the day before the anticipated importation, FDA will substantially increase the number of amendments and updates. For some classes of products – commodity ingredients, for example – the proposed system will guarantee a one hundred percent amendment rate. Similarly, for products originating in Canadian or Mexican facilities located within several hours of the U.S. border, there will be a very high amendment rate. In the case of commodity products, this result will ensue because these articles typically are transported by rail car and the quantity of product cannot reasonably be

known until the rail cars are loaded. Under the proposal, the initial notice must be filed before the rail cars are loaded to permit their departure for the U.S. border promptly after loading. If the notice was not submitted in advance of loading, then the rail cars would be required to be kept either at the loading location or, even worse, at the border point for one to two days. Thus, to protect against that outcome, notice would be filed in advance of loading with the unavoidable result that an amendment will almost always be required. In the case of these types of products, the proposed system thus mandates two notices (initial and amendment) for no valid reason. Products coming from facilities that are close to the U.S. border will, for similar reasons, often require an initial prior notice and an amendment, as well.

Second, and more generally, the requirement that the notice be submitted by noon of the day before the anticipated arrival greatly complicates the notice/amendment/update process and thus increases the likelihood that there will be a greater number of "notice failures" than is otherwise the case. Under the proposal, the need for an amendment must be anticipated and noted on the initial notice. If the need for an amendment was not anticipated, a new notice must be submitted with the attendant delay that will ensue. Conceivably, some persons will decide to routinely indicate that an amendment will be forthcoming – in case one is required – and then to terminate the amendment if it turns out that one is not needed. Neither of these approaches makes sense.

There are similar problems with the update process. Under section 1.294 of the proposal, updates to an initial notice are required if the anticipated port of entry changes or if the anticipated time of arrival is more than one hour earlier or three hours later than expected. The update process could also be used to provide additional information about grower identity.

There are numerous scenarios in which the timing of arrival of a carrier at a port of entry will be different from that anticipated: trucks and trains have mechanical difficulties, traffic is greater or lesser than expected, or weather affects the ability of the carrier to arrive at the anticipated time. Any one or several of these events can cause the difference in the arrival time at the port of entry to exceed one hour early or three hours late and thus to trigger the need for an update. Furthermore, because of the requirement that the notice be provided by noon of the day before the anticipated arrival of the article of food at the port of entry, unexpected days at facilities (problems with production; mechanical problems with trucks that delay loading and departure, for example) will either necessitate frequent updates or new notices altogether.

Under the proposal, the failure to file an update, where one is required, results in the notice being deemed ineffective (section 1.294(d) of the proposal). This requirement will either result in many more updates than FDA's assumes, or many more ineffective notices than is tolerable. Suppose that a facility is located about two hours from the U.S. border and that a facility expects a truck to depart for the border at 2 p.m. on Tuesday. The facility files a notice by noon on Monday for the anticipated 4 p.m. arrival on Tuesday. On Tuesday, when the truck arrives to be loaded, problems are encountered which delay the departure by two hours. At this point, it would appear that the initial notice is still effective, because the truck would ordinarily arrive by 6 p.m., which is within the three-hour window, which FDA has provided. The truck encounters unexpectedly heavy traffic and does not arrive until 7:30 p.m. The truck driver has informed his dispatcher of the delay, which without an update will cause the initial notice to be ineffective (because the arrival time is more than three hours after the anticipated arrival time). Persons employed by the facility to handle notices and updates do not learn of the delay in time to file a timely update. FDA then concludes that the notice has not been effective and, under section 1.278 of the proposal, refuses admission. The truck must then be held at the port of entry or, if so directed by FDA, moved to a secure facility. The release of the truck and the admission of the products contained in it will require the submission of a new notice and the passage of time (two days, in the hypothetical provided). The resulting disruption to the flow of food into the United States seems disproportionate to the offense – an unavoidable thirty-minute delay in the arrival of the product at the port of entry.

If FDA were to abandon the requirement that the notice be filed by noon of the day before the food is scheduled to arrive at the port of entry in favor of a more flexible rolling notice period (four hours before anticipated arrival, for example), these types of problems would largely disappear. Moreover, FDA should provide for more flexibility in terms of the time of arrival at ports of entry, where the actual time differs from the anticipated. A shipment arriving just outside the window for updates should not be deemed to have an ineffective notice.

g. *Food Contact Substances Should Be Exempt*

FDA has proposed to require that prior notice be filed for the importation of food contact articles because those articles are capable of inclusion in the definition of "food." We do not believe that the Bioterrorism Act mandates this outcome. Indeed, to the contrary, we conclude that the available legislative history

supports the conclusion that Congress did not intend for food packaging to be covered by a prior notice when offered for import.

Moreover, under FDA's proposed definition, many common household items, long excluded from FDA scrutiny under the so-called "housewares exemption," would suddenly be subject to prior notice. Companies that have been in business for many years making pots and pans, utensils and the like will, no doubt, be astounded to learn that while FDA pays no substantive attention to their products (that is, does not subject them to scrutiny under the food additive provisions of the law), those products are nevertheless required to be covered by prior notice. There is no purpose in subjecting these products to the prior notice requirement and no value more generally in applying those requirements to food contact materials.

3. *Ways to Create A Workable Prior Notice System*

GMA has compiled numerous suggestions to create a workable prior notice system. These suggestions are summarized in this section of these comments. In compiling these suggestions we have been guided by several principles: (1) enhance the workability of the prior notice system; (2) ensure that the functions of prior notice are achievable; (3) reduce or eliminate burdens of compliance and the risks of disruption; (4) reduce the likelihood of systemic failure.

- **Eliminate Unnecessary Data Elements from Prior Notice**

The data and information required in prior notice should be limited to that specified in the Bioterrorism Act. Duplication with existing Customs information should be avoided. The data needed to identify the article of food to be imported should be narrowed. The fundamental purpose of the prior notice system can be achieved if the notice contains a general description of the article of food to be imported ("bottled juice beverages") rather than the incredibly detailed identification that is called for under the proposal.

- **The Time Periods for Notice Are Too Inflexible**

The notice structure that FDA has proposed is far more burdensome and duplicative than necessary. Much of the burden comes from requirement that the initial notice be filed by noon of the day before the product is anticipated to arrive at the U.S. port of entry and the inevitable need to amend and/or update the initial notice. The burdens associated with the time frames for notice set

forth in the proposal have been described in detail elsewhere in these comments. We turn here to suggested solutions to those problems.

First, the notice period should be a rolling 4-8 hour period before the product is expected to arrive at the port of entry. The shorter notice should apply in the case of product arriving from contiguous countries, especially by truck or rail and the 8-hour period should apply to product arriving by other means or from other places. Shortening the notice period will enable facilities to better ensure that the notice that is provided is complete and accurate and will minimize the need for amendments and updates. Further, we suggest that FDA adopt a 24-hour notice period for cargo arriving by ship, which is the current Customs Service advance manifest requirement. Additionally, we believe that a "wheels up" period is appropriate for air shipments, which would eliminate the need for amendments in the case of air shipments.

In the case of food arriving by ship, the four-hour window for arrival at the port of entry is unrealistic. Sea vessel schedules change constantly due to weather, events that occur in other ports, loading/unloading equipment issues at docks, boats running aground, and numerous other unforeseen circumstances. FDA should provide for a six-hour window in the case of food arriving by ship. The additional two hours would reduce the frequency of updates for late arriving ships but would not impede FDA's ability to have inspectors available if it wishes to examine the cargo. When a vessel arrives in port, it must be unloaded and FDA must give permission to proceed before the importer receives access to the goods. Thus, even with an expanded arrival window, FDA inspectors will have ample opportunity to access the cargo for inspection.

Second, FDA should provide for an optional[2] notice for regular recurring shipments of essentially the same or a limited array of articles of food. If, for example, FDA allowed a monthly notice for shipments from a facility that produces an array of snack foods with the dates and approximate times of anticipated arrival at the U.S. border (and, of course, a description of the products to be imported), companies would be spared the task of daily notices and amendments, while FDA would be given even more advance notice of imports than even the Bioterrorism Act contemplates.

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[2] The Bioterrorism Act does not permit FDA to require prior notice more than five days before the food is offered for import (section 801(m)(2)(A) of the FDC Act). There is nothing in the Bioterrorism Act, however, that precludes FDA from providing for an optional notice period that exceeds five days.

Thus, for example, if a company knows that during a coming month, it will have six trucks per day, every day of the month, leave a facility for the United States, it should be able, at its option, to file a single "monthly" notice instead of the 180 notices that would otherwise be required. Such a company could then use the amendment and update process to more fully describe the articles of food and to account for changes in the scheduled deliveries that occur during the month. If adopted, this approach would substantially ease the burdens of the daily notice requirement but not impede the functioning of the notice system. Indeed, FDA would gain more advance notice of food to be imported, rather than less.

Third, FDA should provide for an additional optional advanced notice to handle the less frequent but periodic shipments of the same article of food such as an ingredient that is imported four times per year from the same supplier, entering through the same port of entry and destined for the same U.S. facility. In this circumstance, the FDA should allow a single annual notice, subject to needed amendment or update, to satisfy the prior notice requirement. As in the case of the frequent, ongoing shipments during a month, this approach will also provide FDA will more notice than is contemplated under the Bioterrorism Act.

- **Provide for a Single Prior Notice to Cover a Shipment of Multiple Articles of Food**

Under the proposal, FDA takes the position that the requirement for prior notice applies to "each article of food" and not to a shipment of food. (See preamble discussion at 68 Fed. Reg. 5435.) From the conclusion that a prior notice is required for each article of food, FDA states that "any food product identified by a specific FDA product code and quantity description produced by a single manufacturer...associated with a single entry line number...must be covered by a prior notice."

We do not understand the logic of this conclusion. The Bioterrorism Act does not state that a separate prior notice must cover each article of food. It is entirely consistent with the Bioterrorism Act to permit a single prior notice to cover all of the articles of food in a single shipment. Such an approach minimizes the number of prior notices and amendments and reduces the likelihood of problems with the prior notice system.

For example, under the proposal, if a transportation vehicle is delayed beyond the three-hour window that FDA proposes to allow, a prior notice will have covered each article of food on the vehicle. The information about the late

arrival must be communicated to each party that previously filed a notice covering an article of food on the vehicle. Each of those persons must file an update. What happens if one person does not file an update? Under our suggestion, there would only be a single prior notice and a single update, yet a prior notice within the meaning of the Bioterrorism Act would cover each article of food.

- **Quality Analysis or Research and Development Samples Should Be Exempt From Prior Notice or, Alternatively, Covered By a "Blanket Notice"**

There are currently located in the United States a large number of quality analysis and research and development facilities that provide valuable and commercially important services to many multinational food companies. These facilities assist companies in a wide array of activities, from ingredient and product development to quality control and assurance. Many companies have organized these QA and R&D activities so that worldwide analyses and testing is done in the United States. The activities that are conducted at these facilities often have a direct bearing on food safety and security. If the prior notice proposal does not provide an accommodation for QA and R&D samples, there will be a strong incentive for companies to relocate these facilities to non-U.S. locations.

As proposed, the prior notice requirement will impede the operations of these U.S.-based QA and R&D operations. Some of these operations receive thousands of shipments each year of ingredients and products for various types of testing and analyses. The samples that are sent to these facilities for testing and analyses are typically small quantities. The samples are sent by foreign affiliates and unrelated companies. It will be very difficult, if not impossible, for all of these shipments of samples to be covered by an individual prior notice.

We suggest two approaches that would solve this problem: (1) FDA could exempt QA and R&D samples so long as they are labeled as such and are shipped to a registered QA or R&D facility; or (2) FDA could permit a "blanket" annual prior notice for QA and R&D samples shipped to a registered QA or R&D facility, so long as the samples are labeled as such.

- **The Amendment and Update Process Should be More Flexible**

Under the proposal, companies may only amend a notice once and then only if the potential need for the amendment was known at the time that the initial

notice was filed. The proposal appears to contemplate the possibility that multiple updates could be filed and cause a prior notice to be effective.

In the case of amendments, however, the limitations that FDA proposes to impose substantially diminish the utility of the amendment option.

First, amendments should be permitted even where the need for the amendment was not known at the time that the initial notice was filed. The assumptions that FDA relied on in developing the proposal – that the initial notice and limited amendment opportunity would adequately cover the range of situations that arise in the movement of product from its place of production to the U.S. border – are not valid. If the amendment process remains as limited as it is in the proposal, there will likely be considerable disruption to the process of importing food into the United States without any compensating benefit to the security of the food supply. If notice is required by noon of the day before the shipment is anticipated to arrive at the U.S. port of entry (and we suggest that it not be required at that time), there is a compelling need to permit amendments to that notice where there are changes in the mix of products that were loaded onto the carrier which could not have reasonably been anticipated. If amendments are not allowed when that happens, but, instead, a new notice is required, the delays in getting product to customers will be frequent and costly.

Second, multiple amendments should be permitted. For example, the proposal does not appear to provide for the correction of errors in a notice. Whether the data and information are as expansive as FDA has proposed or narrow as GMA urges, there will still be inadvertent errors made in the notice process. Filers should be able freely to amend notices to provide corrected or updated information about the articles of food described in the initial notice.

Finally, it is important that FDA provide a mechanism to correlate amendments and updates to the initial notice. Without such a mechanism, neither the person filing the notice nor the FDA will be able to make any sense of the information provided and the likelihood that food will arrive at ports of entry with an apparent notice problem will increase.

- **Inadequate Notice Should Be Subject to Immediate Correction**

It is a virtual certainty in any notice system, be it the overly complex one that FDA has proposed or the simpler one along the lines of that suggested in these comments, that there will be occasions when food arrives at the border without

an effective prior notice. Under the proposal, it appears that when this happens, the product will automatically be refused admission (as the Bioterrorism Act mandates). What is unclear, however, is how quickly will products be released once the problem with the notice is cured.

The final regulation should provide that ordinarily, when a notice has been filed but, upon arrival of the food, is deemed inadequate, the food would be cleared promptly (within 24 hours) once the notice problem is fixed. When there is only a technical violation of the notice requirements, the food, which is the subject of the notice, should be permitted entry into the United States as soon as the notice problem has been addressed. Food with limited shelf life, which is not promptly cleared once the notice problem is fixed, may become unsaleable. Where food arrives without notice at all or with major deficiencies in the notice, we recognize that the process of filing a notice or correcting errors will take time and that such a pattern may reasonably cause FDA to decide to examine closely the shipment.

- **Connect the Registration and Prior Notice Systems**

One of the ways in which the burdens of the prior notice system could be reduced is to connect the registration and prior notice systems. If the two systems operated in a connected fashion, a filer of a prior notice would need only enter the appropriate facility registration number and the prior notice system could then populate the appropriate fields in the prior notice electronic filing system. Some companies expect to file thousands or tens of thousands of notices each year; eliminating the need to enter for each prior notice, information that has already been recorded into the facility registration system would greatly reduce the data entry burden as well as reduce the potential for data entry errors.

- **C-TPAT Participating Companies Should Be Subject to Reduced Notice Requirements**

The Customs Service has established a program "Customs-Trade Partnership Against Terrorism," or C-TPAT for short, which is an initiative between business and the federal government to protect global commerce from terrorism. The C-TPAT program requires participating importing companies to establish policies to enhance their own security practices and those of their business partners involved in the supply chain. Imports from companies that chose to participate in the program and are subsequently determined by the Customs Service to have met its requirements, are given expedited processing at ports of entry.

Many C-TPAT participants have facilities near the U.S. border and have a high volume of products that enter the United States. The product distribution systems of these companies are set up to rely on the fast movement of low risk products. In some cases, the time from receipt of an order until arrival at the border is two hours. In many instances, the time from when a truck is loaded and its contents finalized until arrival at the border is two hours.

FDA should embrace the C-TPAT program and allow companies that participate in that program to submit a "short form" prior notice and to be able to submit an initial prior notice within 2 hours of the time of anticipated arrival of product at a port of entry. FDA's prior notice system could readily be programmed to accept more limited data and a shorter time period for the notice from companies that are C-TPAT participants.

There are advantages to this approach. First, given the requirements of C-TPAT participation, food offered for import from C-TPAT-participating companies is far less likely to be of concern to FDA than food from non-participating companies. The purpose of the prior notice system is to aid FDA in deciding how to apply limited resources to the inspection and examination of millions of entries of food into the United States each year. C-TPAT companies should automatically receive lower priority from FDA (consistent with the commitment of the Customs Service to give the products of these companies expedited processing). One simple way for FDA to give a lower priority to products from C-TPAT companies would be to accept less information in the notice and less time to evaluate the notice. This would free up the time of FDA import specialists while preserving the integrity of the prior notice system.

4. *Conclusions*

GMA does not underestimate the difficulty that confronts FDA in creating a prior notice system that is capable of efficiently handling millions of occasions each year in which food is imported into the United States. We are concerned, as these comments reflect, that in designing the prior notice system, FDA has made a series of decisions that cause the resulting system to be overly complex and rigid. FDA has failed to evaluate properly the effect that the proposed system will have on commerce. It is not hyperbolic to suggest that if FDA adopts the system, as proposed, serious disruption in commerce will ensue. GMA is not confident that each of the pieces of the proposed prior notice system will work as designed; a failure in one point will cause a ripple effect throughout the entire system. Systemic failure is a real possibility.

We strongly suggest that FDA re-examine the proposal with the goal of commercial practicality and feasibility to reduce the likelihood of overall systemic failure. We have identified numerous serious problems with the proposal in these comments and provided suggested approaches to address them. But, FDA should be clear: we do not think that making changes on the margins can cure the problems with the proposed prior notice system. GMA member companies have an abiding interest in a workable prior notice system; we do not believe, however, that the current proposal will work. FDA must revise the proposal to make it simpler and more flexible. FDA must also pay greater attention to what is commercially feasible.

GMA commends FDA for its outreach program to various stakeholders. In various forums and on countless occasions, FDA personnel have been available to explain the proposal, to respond to questions, and to listen to concerns. GMA urges FDA to remain accessible during the time in which it is evaluating comments and to continue to include the stakeholders in the ongoing process of developing a workable prior notice system.

Sincerely yours,

James H. Skiles
Vice President, General Counsel